contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: May 24, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016–12637 Filed 5–27–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–3327]

Agency Information Collection Activities; Proposed Collection; Comment Request; E6(R2) Good Clinical Practice; International Council for Harmonisation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collections of information marked as ''ADDENDUM'' in the draft guidance entitled ''E6(R2) Good Clinical Practice'' (E6(R2) draft guidance). The E6(R2) draft guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The E6(R2) draft guidance amends the guidance entitled ''E6 Good Clinical Practice: Consolidated Guidance'' (E6(R1) consolidated guidance), issued in April 1996, to encourage implementation of improved and more efficient approaches to clinical trial design, conduct, oversight, recording, and reporting while continuing to ensure human subject protection and data integrity. Standards regarding electronic records and essential documents intended to increase clinical trial quality and efficiency have also been updated. The E6(R2) draft guidance was intended to improve clinical trial quality and efficiency while maintaining human subject protection. This notice solicits comments on the collection of information in the draft guidance concerning the development of a system to manage quality, as well as information to include in a clinical study report about the quality management approach.

DATES: Submit either electronic or written comments on the collection of information by August 1, 2016 on the ''ADDENDUM'' sections of the E6(R2) draft guidance.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submission'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–D–3327 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; E6(R2) Good Clinical Practice; International Council for Harmonisation.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food

and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

E6(R2) Good Clinical Practice Draft Guidance; International Council for Harmonisation OMB Control Number 0910–NEW

I. Background

In the **Federal Register** of September 29, 2015 (80 FR 58492), we announced the availability of and requested public comments on the E6(R2) draft guidance. The draft guidance is the product of the ICH E6 Expert Working Group of the ICH. The E6(R2) draft guidance provides additions to the E6(R1) consolidated guidance that are identified as ''ADDENDUM'' and marked with vertical lines on both sides of the text. The additions are intended to encourage implementation of the described approaches and processes to improve the quality and efficiency of clinical trials while maintaining the protection of human subjects. The E6(R2)draft guidance includes information collection provisions that are subject to review by OMB under the PRA. This **Federal Register** notice begins the process of requesting public comment and obtaining OMB approval for those information collections that are new and are not already covered by previously approved collections of information.

II. Burden Estimates for the E6(R2) Draft Guidance

The E6(R2) draft guidance recommends that sponsors develop and maintain a system to manage quality when designing, conducting, recording, evaluating, reporting, and archiving clinical trials. The draft guidance also recommends that the sponsor describe the quality management approach implemented in the trial and summarize important deviations from the predefined quality tolerance limits in the clinical study report. We are requesting OMB approval for the following collections of information identified in the ''ADDENDUM'' sections of the E6(R2) draft guidance and are inviting public comments on these sections.

In table 1 of this document, we estimate that approximately 1,457 sponsors of clinical trials of human drugs will develop approximately 1,457 quality management systems per year (as described in section 5.0 of the E6(R2) draft guidance). We further estimate that it will take sponsors approximately 60 hours to develop and implement each quality management system, totaling 87,420 hours annually. These estimates are based on the number of annual investigational new drug applications (IND) and new drug applications (NDA) submitted to the Center for Drug Evaluation and Research in previously approved collections of information. The estimated number of sponsors that will develop a quality management system as described in the guidance, as well as the estimated number of hours it will take, is based on FDA interactions with sponsors about activities that support drug development plans.

In table 2 of this document, we estimate that approximately 1,457 sponsors of clinical trials of human drugs will describe the quality management approach implemented in a clinical trial and summarize important deviations from the predefined quality tolerance limits in a clinical study report (as described in section 5.0.7 of the E6(R2) draft guidance). We further estimate that sponsors will submit approximately 4.6 responses per respondent and that it will take sponsors 3 hours to complete this reporting task, totaling 20,107 reporting hours annually. These estimates are based on past experiences with IND, NDA, and previously approved collections of information.

In table 3 of this document, we estimate that approximately 218 sponsors of clinical trials of biological products will develop approximately 218 quality management systems per year (as described in section 5.0.7 of the E6(R2) draft guidance). We further estimate that it will take sponsors approximately 60 hours to develop and implement each quality management system, totaling 13,080 hours annually. These estimates are based on past experiences with INDs, biologics license applications (BLA), and previously approved collections of information.

In table 4 of this document, we estimate that 218 sponsors of biological products will describe the quality management approach implemented in a clinical trial and summarize important deviations from the predefined quality tolerance limits in a clinical study report (as described in section 5.0.7 of the E6(R2) draft guidance). We further estimate that sponsors will submit approximately 3.69 responses per respondent and that it will take sponsors 3 hours to complete this reporting task, totaling 2,413 reporting hours annually. As described previously, these estimates are also based on past experiences with IND, BLA, and previously approved collections of information.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR HUMAN DRUGS [1]

E6(R2) Good Clinical Practice; International Council for Harmonisation; Draft Guidance for Industry	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Section 5.0—Quality Management (including sections 5.0.1 to 5.0.7)	1,457	1	1,457	60	87,420

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR HUMAN DRUGS [1]—Continued

E6(R2) Good Clinical Practice; International Council for Harmonisation; Draft Guidance for Industry	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Developing a Quality Management System.					

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS [1]

E6(R2) Good Clinical Practice; International Council for Harmonisation; Draft Guidance for Industry	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Section 5.0.7—Risk Reporting ..... Describing the Quality Management Approach Implemented in a Clinical Trial and Summarizing Important Deviations From the Predefined Quality Tolerance Limits in a Clinical Study Report.	1,457	4.6	6,702	3	20,107

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR BIOLOGICS [1]

E6(R2) Good Clinical Practice; International Council for Harmonisation; Draft Guidance for Industry	Number of recordkeepers	Number of records per recordkeeper	Total records	Average burden per record	Total hours
Section 5.0—Quality Management (including 5.0.1 to 5.0.7) ..... Developing a Quality Management System.	218	1	218	60	13,080

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICS [1]

E6(R2) Good Clinical Practice; International Council for Harmonisation; Draft Guidance for Industry	Number of responses	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Section 5.0.7—Risk Reporting ..... Describing the Quality Management Approach Implemented in a Clinical Trial and Summarizing Important Deviations From the Predefined Quality Tolerance Limits in a Clinical Study Report.	218	3.69	804	3	2,413

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The collections of information included in the sections marked as ''ADDENDUM'' in the E6(R2) draft guidance also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information found in 21 CFR part 11 have been approved under OMB control number 0910–0303; the collections of information found in 21 CFR part 312 have been approved under OMB control number 0910–0014; and collections of information found in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information found in 21 CFR part 601 have been approved under OMB control number 0910–0338.

Dated: May 24, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–12651 Filed 5–27–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–P–0403]

Determination That LEVOTHROID (Levothyroxine Sodium) Tablets, 0.025 Milligram, 0.05 Milligram, 0.075 Milligram, 0.088 Milligram, 0.112 Milligram, 0.125 Milligram, 0.137 Milligram, 0.15 Milligram, 0.175 Milligram, 0.1 Milligram, 0.2 Milligram, and 0.3 Milligram, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that LEVOTHROID